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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Date: June 11, 2014

Subject: **Deltamethrin.** Revised Residential Exposure Assessment to Support A Tolerance Without a US Registration on Imported Fish.

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Introduction

The Registration Division (RD) requested that the Health Effects Division (HED) conduct an exposure and risk assessment for the proposed use of the synthetic pyrethroid deltamethrin to establish a tolerance on imported fish. In conjunction with the review of the proposed new use, HED revised the residential assessment of registered uses for the purpose of completing an

aggregate risk assessment. The assessment and revisions incorporate the use of the following: (1) the 2012 Residential Standard Operating Procedures (SOPs); (2) a two month dislodgeable residue study of deltamethrin in dogs treated with impregnated dog collars (3) updated toxicological endpoints and hazard characterization; and (4) EPA's justification for reducing the Food Quality Protection Act (FQPA) safety factor of 10X to 3X for infants and children less than 6 years of age and to 1X for the general population (including children 6 years of age and older).

It is HED policy to use the best available data to assess exposure. Several sources of generic data were used in this assessment as surrogate data in the absence of chemical-specific data, including: the Outdoor Residential Exposure Task Force (ORETF) database; and the Residential SOPs (Lawns/Turf, Indoor Environments, Pets, and Treated Paints and Preservatives). Some of these data are proprietary, and subject to the data protection provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Note: This memorandum was reviewed by the Exposure Science Advisory Committee (ExpoSAC) on June X, 2014.

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1.0 Executive Summary

Deltamethrin [(1R,3R)-R-cyano(3-phenoxyphenyl)methyl 3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate)] is currently registered for use on a wide variety of food/feed crops, stored grains, and food/feed handling establishments. Numerous formulations of deltamethrin are also registered for use in commercial and residential outdoor and indoor sites, as well as in paint additive and pet products.

The Registrant, Pharmaq, has requested that an import tolerance be established for the use of deltamethrin on imported fish. There is no occupational exposure associated with this proposed tolerance since the use is for import only. Therefore, an occupational exposure assessment is not included in this assessment. Furthermore, there are no new residential uses associated with this regulatory action; however, a revised assessment of the registered residential uses is provided for the purpose of updating the aggregate risk assessment. This revision and the assessment for the new product incorporate the following:

1. Use of the 2012 Residential SOPs,
2. Updated toxicological endpoints and hazard characterization, and
3. EPA's justification for reducing the FQPA safety factor of 10X to 3X for infants and children less than 6 years of age and to 1X for the general population (including children 6 years of age and older).
4. Submission of chemical specific residue transfer study for pet collar.

Hazard Characterization

The hazard characterization of deltamethrin has been revised since the most recent comprehensive human health risk assessment (D. Dotson, D262496, Nov. 15, 2004) performed to evaluate several proposed agricultural and existing residential uses, and since a response to a tolerance petition for a new agricultural use (M. Collantes, D335134, Aug, 13, 2009). The Toxicological Science Advisory Council (ToxSAC) concluded that systemic toxicity via the dermal route of exposure is not anticipated. No treatment-related findings were observed at the limit dose; therefore, a quantitative dermal exposure assessment is not required. The same dose and endpoint based on decreased motor activity observed in an acute oral rat study is being used to estimate short-term incidental oral and inhalation exposure scenarios. A route-specific inhalation study is not available for deltamethrin; however, HED determined that a subchronic inhalation study is not required. Therefore, an additional database uncertainty factor (UF) is not required (HASPOC, TXR #) for the lack of a sub-chronic inhalation toxicity study. A bench mark dose (BMD) analysis was conducted for the acute oral rat study and the lower confidence limit (BMDL) of 1.49 mg/kg/day and is protective of potential offspring effects observed in the developmental neurotoxicity (DNT) and 2-generation reproductive study. It is also used to extrapolate inhalation risk because of the overall robust nature of the study and the lack of increased hazard from repeated/chronic exposure to deltamethrin. Absorption and toxicity via the inhalation route are assumed to be equal to toxicity via the oral route.

HED is reducing the FQPA safety factor from 10X to 1X for women of child-bearing age as well as for all adult populations including children > 6 years based on the absence of pre-natal sensitivity observed in the guideline studies and the supporting literature. However,

HED is retaining a 3X uncertainty factor to protect for exposures of children less than 6 years of age based on increased quantitative susceptibility seen in studies on pyrethroid pharmacokinetics and the increased quantitative juvenile susceptibility observed in high doses studies, such as the deltamethrin guideline DNT and 2-generation reproduction studies. The FQPA safety factor is then combined with the traditional 10X uncertainty factores for intraspecies variability and interspecies extrapolation to arrive at the level of concern at the level of concern (LOC) for risk assessment (i.e. 300 for children < 6 years of age, and 100 for children 6 years of age and older and adults).

Deltamethrin is classified as "not likely to be carcinogenic to humans."

Residential Exposure

There are no new proposed residential uses associated with this action. However, this document includes a revised handler and post-application exposure assessment for existing residential uses (i.e., indoor, outdoor, pet, and paint additive) that were evaluated in the 2004 occupational and residential exposure (ORE) assessment, and have been reassessed to reflect updates to HED's 2012 Residential SOPs[1], along with policy changes for body weight assumptions and updated inhalation and incidental oral toxicological endpoints and uncertainty factors (UFs).

All the residential handler scenarios resulted in inhalation risk estimates greater than the LOCs and are not of concern (i.e., MOEs are ≥ 100). Post-application inhalation exposure for adults and children is anticipated to be negligible for the representative residential registered uses; therefore, a quantitative post-application inhalation exposure assessment was not performed.

All the representative indoor/outdoor and pet residential use scenarios resulted in incidental oral (hand-to-mouth) post-application risk estimates for children ranging from an MOE of 630 to 400,000 and are not of concern.

The revised residential exposure risk estimates will affect the aggregate human health risk assessment for deltamethrin. All residential scenarios selected for the aggregate assessment resulted in MOEs greater than the LOC and are not of concern.

Episodic Granular Ingestion

The default granular ingestion rate of 0.3 grams/day was adjusted to 0.14 grams/day (1/10 of the product) to reflect the amount of product applied on a per area basis (3 lb/1000ft^2) as explained in the Residential SOP for Turf and Lawns. The reduction in ingestion rate resulted in an estimated dose of 0.0127 mg/kg/day and a MOE of 120 which is below the LOC for incidental ingestion of granules. In order to achieve an MOE greater than the LOC (MOE ≥ 300) based on amount of product applied per area, the application rate would need to be reduced from the current rate of 0.000003 lb ai/ft^2 to 0.000001 lb ai/ft^2. However, ingestion of granules is considered an episodic (or acute) event and not a routine behavior for children. Since HED does not believe that this would occur on a regular basis, the scenario is considered to be an acute poisoning rather than a short-term exposure typically assessed in HED's human health risk assessments. Furthermore, the registered label instructs the user to thoroughly water treated

[1] Available: http://www.epa.gov/pesticides/science/residential-exposure-sop.html

areas after application so that both granules and lawns are moistened to ensure granules dissolve properly.

Cumulative Risk Assessment

Typically, proposed new residential uses of pyrethroid chemicals are evaluated to determine whether they would contribute significantly to or change the overall findings in the 2011 pyrethroid Cumulative Risk Assessment (CRA). Deltamethrin was included in a cumulative risk assessment for pyrethrins and pyrethroids (D394576, K. Whitby, 10/4/2011). In the cumulative assessment, residential exposure was the greatest contributor to the total exposure. However, in the pyrethroid CRA, the Agency focused on the four main pyrethroid residential use scenarios – turf, pets, gardens, and indoor (broadcast, fogger and crack and crevice applications).

There are no new or proposed residential uses associated with deltamethrin since the 2011 CRA. Therefore, the proposed new (i.e., request for tolerance on imported fish) use and the currently registered residential uses for deltamethrin will have no impact on the residential component of the cumulative risk estimates. Additionally, the POD selected for deltamethrin is specific to deltamethrin, whereas the POD selected for the cumulative assessment was based on common mechanism of action data that are appropriate for all 20 pyrethroids included in the cumulative assessment.

Occupational Exposure

There are no occupational scenarios associated with the proposed tolerance on imported fish; therefore, an occupational exposure assessment is not required for this action.

Human Studies Review

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include studies from the Residential SOPs (Turf/Lawn, Indoor Environments, and Pets, Impregnated Materials and Treated Paints and Preservative), are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency website[2].

2.0 Risk Assessment Conclusions and Recommendations

2.1 Summary of Risk Estimates

There are no occupational or new residential uses associated with the proposed tolerance for imported fish. All handler inhalation risks for registered residential uses resulted in estimated MOEs > 4,300 and are not of concern. The post-application incidental oral (hand-to-mouth) estimated MOEs resulting from the use of indoor/outdoor and pet registered residential uses ranged from 630 to 24,000 for children < 6 years of age and are not of concern.

[2] http://www.epa.gov/pesticides/science/handler-exposure-data.html and http://www.epa.gov/pesticides/science/post-app-exposure-data.html

2.2 Label Recommendations from Occupational/Residential Assessment

None

2.3 Data Deficiencies and Requirements

There are no data deficiencies associated with the proposed tolerance for use of deltamethrin on imported fish. However, HED has identified the need for a turf transferable residue (TTR) study to support the existing uses of deltamethrin. This deficiency was not identified in the 2010 human health assessment scoping document in support of Registration Review, and therefore the Data Call-In for deltamethrin did not include the required TTR study.

Since the estimated residential turf post-application exposure for [residential turf/mower/golf course] using default TTR values for deltamethrin is not minimal in comparison to the level of concern (i.e., the calculated MOE is not greater than 10 times higher than the level of concern, MOE = 750 compared to the LOC of 3000), future refinements of this post-application exposure for deltamethrin may be necessary due to increased use of deltamethrin or advances in EPA risk assessments. Therefore, EPA is requiring the 40CFR TTR data requirement to facilitate any necessary exposure assessments refinements and to further EPA's general understanding of the availability of turf transferable pesticide residues.

3.0 Hazard Characterization

Deltamethrin is a member of the synthetic pyrethroid class of insecticides. Pyrethroids have historically been classified into two groups, Type I and Type II, based on chemical structure and toxicological effects. Type I pyrethroids, which lack an alpha-cyano moiety, induce a syndrome consisting of aggressive sparring, altered sensitivity to external stimuli, hyperthermia, and fine tremor progressing to whole-body tremor and prostration (T-syndrome). Type II pyrethroids, which contain an alpha-cyano moiety, produce a syndrome in rats that includes pawing, burrowing, salivation, hypothermia, and coarse tremors leading to choreoathetosis (CS-syndrome) (Verschoyle and Aldridge 1980; Lawrence and Casida 1982). Deltamethrin is a type II pyrethroid. The adverse outcome pathway (AOP, based on the Bradford-Hill criteria) shared by pyrethroids involves the ability to interact with voltage-gated sodium channels (VGSCs) in the central and peripheral nervous systems, leading to changes in neuron firing and, ultimately, neurotoxicity.

Deltamethrin has been evaluated for a variety of toxic effects in experimental toxicity studies. Deltamethrin targets the nervous system. Neurotoxicity was observed throughout the database and effects were seen across species, sexes, exposure durations and routes of administration. Clinical signs characteristic of Type II pyrethroids, such as increased salivation, altered mobility/gait, and tremors were seen in experimental toxicology studies including neurotoxicity studies (acute and subchronic) in rats, subchronic and chronic studies in dogs and rats, and developmental and reproduction studies in rats. In addition to the clinical signs noted above, increased sensitivity to external stimuli, abnormal vocalization, and decreased fore- and hind-limb grip strength were commonly observed in the database.

Acute Toxicity

Deltamethrin has either moderate (Toxicity Category II) or minimal (Toxicity Category IV) toxicity via the oral route of exposure in acute lethality studies, moderate acute toxicity via the inhalation (Toxicity Category II/III) route of exposure and minimal toxicity via the dermal (Toxicity Category III) route of exposure. It is minimally irritating to the eye (Toxicity Category III) and non-irritating to the skin (Toxicity Category IV). It is not a skin sensitizer.

Table 3.0. Acute Toxicity Profile – Deltamethrin Technical.

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral [rat]	41651019	LD_{50} >5000 mg/kg in 1% aqueous methyl cellulose	IV
		00070734	LD_{50} = 66.7 mg/kg = 86 mg/kg in polyethylene glycol LD_{50} = 128.5 mg/kg = 138.7 mg/kg in sesame oil	II
870.1200	Acute dermal [rat]	41651020	LD_{50} >2000 mg/kg	III
870.1300	Acute inhalation [rat]	41651021	LC_{50} >2.2 mg/L	III
870.1300	Acute inhalation [rat]	00070734	LC_{50} >0.6 mg/L	II
870.2400	Acute eye irritation [rabbit]	41651022	Mild/moderate irritant	III
870.2500	Acute dermal irritation [rabbit]	41651023	Not an irritant	IV
870.2600	Skin sensitization [Guinea pig]	41651024	Not a sensitizer	N/A

Toxicological PODs Used for Risk Assessment

The hazard characterization of deltamethrin has been revised since the most recent comprehensive human health risk assessment (Memo, D262496, D. Dotson, et, al., 11/15/2004), and a response to a tolerance petition for a new agricultural use on flax (Memo, D335134, D. Dotson, et, al., 8/11/2009). The toxicity database for deltamethrin is largely complete including a recently submitted immunotoxicity study which demonstrates no evidence that deltamethrin directly targets the immune system.

Previously, in 2009 a dermal endpoint and dose were selected for infants/children based on decreased motor activity observed in an acute oral study in rats (Wolansky et al., 2006). The decision to conduct a dermal risk assessment was based on the observed susceptibility of offspring in several literature studies, and due to the fact that the dermal study did not assess neurotoxic parameters. Since then, HED concluded that systemic toxicity via the dermal route of exposure is not anticipated. No treatment-related findings were observed at either the limit dose of 1000 mg/kg/day, nor up to a dose of 2000 mg/kg/day in the 21-day dermal study. Therefore, a quantitative dermal assessment was not performed. Typically pyrethroids have a low absorption value of $\leq$ 5% and a high rate of metabolism. Deltamethrin had a slightly higher absorption value of 11.3%, although the majority of the radioactivity measured was at the skin site (10.6%). This is typical of the pyrethroids, as they are lipophilic and much of the radioactivity measured

in the skin of dermal penetration studies with pyrethroids is captured in the upper dermal layers and not available for absorption or systemic circulation.

For the purpose of assessing exposure resulting from the use of registered residential products, HED has used the endpoint and dose selected from the oral Wolansky study for incidental oral, and inhalation exposure and risk assessments. Due to the metabolic profile of deltamethrin, which indicates rapid elimination from the body, HED notes that increased toxicity is not expected with an increase in the duration of exposure, which is typical for pyrethroids. Therefore, for the purpose of this exposure assessment, only single day risk assessments need to be conducted for deltamethrin, and these are protective of scenarios in which exposure occurs for multiple days.

A 21-day inhalation study was submitted for deltamethrin, but it was classified as unacceptable, non-guideline; however, a new study was not required in conjunction with Registration Review. Subsequently, the Hazard and Science Policy Council (HASPOC) determined that a subchronic inhalation study in rats is not required (TXR #0056944). As a result, the oral BMDL ISD of 1.49 mg/kg/day from the Wolansky acute rat study was selected to estimate inhalation exposure and risk.

Deltamethrin is classified as "not likely to be carcinogenic to humans" because there was no evidence of carcinogenicity in the combined chronic/carcinogenicity study in rats or the carcinogenicity study in mice. Furthermore, in a battery of mutagenicity studies, there was no evidence of a mutagenic effect.

3.1 FQPA and Uncertainty Factor Considerations

Previously, the 10X FQPA Safety Factor (SF) was retained for children, and was applied to all exposure scenarios involving children based on literature studies indicating a possibility of increased sensitivity to neurotoxic effects of deltamethrin in juvenile rats at high doses. The studies indicate that children have a diminished capacity to detoxify deltamethrin relative to adults. In the cumulative risk assessment for pyrethroids (D394576, K. Whitby, 10/4/2011), HED determined that the 10X FQPA factor could be reduced. In light of the literature studies and the uncertainty regarding the protectiveness of the intraspecies uncertainty factor in the absence of additional data, the FQPA factor has been reduced to 3X for infants and children < 6 years of age pending receipt of additional toxicity data supporting further reduction of the FQPA factor for infants and children. For adults and children 6 years of age and older, the available data support reduction of the FQPA SF to 1X.

The FQPA safety factor is then combined with the traditional uncertainty factors of 10X for inter-species extrapolation and 10X for intra-species variability to arrive at the level of concern at the level of concern (LOC) for risk assessment (i.e. 300 for children < 6 years of age, and 100 for children 6 years of age and older and adults). Scenarios resulting in MOEs less than 300 for children < 6 years old, and less than 100 for adults or children ≥ 6 years old, represent risk estimates of concern.

A summary of the toxicological doses and endpoints for residential exposure scenarios is provided in **Table 3.2**.

Table 3.2. Summary of Toxicological Doses and Endpoints for Deltamethrin for Use in Non-Occupational Human Health Risk Assessments.

Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Children<6 years old)	Wolansky BMDL1SD = 1.49 mg/kg	UF_A = 10X UF_H = 10X FQPA SF = 3X	Acute RfD = 0.005 mg/kg aPAD =0.0017 mg/kg/day	Wolansky BMD1SD = 2.48 mg/kg based on decreased motor activity
Incidental Oral Short-term (1-30 days)	Wolansky BMDL1SD = 1.49 mg/kg	UF_A= 10x UF_H=10x FQPA SF=3x	Residential LOC for MOE = 300	Wolansky BMD1SD = 2.48 mg/kg based on decreased motor activity
Dermal Short-term (1-30 days) Children ≥6 years old and adults	Systemic toxicity via the dermal route of exposure is not anticipated. No treatment-related findings were observed at the limit does of 1000 mg/kg/day and therefore, a quantitative dermal assessment is not required.			
Dermal Short-term (1-30 days) (Children <6 years old)				
Inhalation Short-term (1- 30 days) (Children ≥ 6 years old and adults)	Wolansky BMDL1SD = 1.49 mg/kg	UF_A= 10x UF_H=10x FQPA SF=1x	Residential LOC for MOE = 100	Wolansky BMD1SD = 2.48 mg/kg based on decreased motor activity
Inhalation Short-term (1-30 days) (Children <6 years old)	Wolansky BMDL1SD = 1.49 mg/kg	UF_A= 10x UF_H=10x FQPA SF= 3x	Residential LOC for MOE = 300	Wolansky BMD1SD = 2.48 mg/kg based on decreased motor activity
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. MOE = margin of exposure. LOC = level of concern.

Absorption:

Since no inhalation absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure.

Body Weight:
The standard body weight for the general population (80 kg) was used for all exposure scenarios covered in this risk assessment since the endpoints selected were not developmental and/or fetal effects. A body weight of 11 kg was used for children under the age of 6 years old.

4.0 Use Profile

There are no occupational or new proposed residential uses associated with this action for establishing a tolerance on imported fish. However, deltamethrin is registered to control a variety of indoor and outdoor pests found on turf, in homes, and in commercial settings, including food handling establishments; as well as in pet and paint additive products. For the purpose of updating the aggregate human health risk assessment, only previously assessed representative residential uses have been re-evaluated using the revised 2012 Residential SOPs.[3] A more comprehensive assessment may be completed during Registration Review. A summary of the registered uses is provided in **Table 4.1**.

Table 4.1. Summary of Registered Residential Uses for Deltamethrin.

Method of Application	Product and Formulation (Reg. No.)	Application Rate	Maximum No. Applications per Season	Maximum Seasonal Application Rate (lb ai/A)	Use Directions, Application Timing, Type and Limitations
Aerosol Spray	D-Force Insecticide 0.06% ai (279-9554)	0.00075 lb ai/can	NA	Continues killing insects up to 8 weeks	For indoor and outdoor use as a spot or crack and crevice use. Also apply to mattress, especially tufts, folds and edges for control of bed bugs. Spray surface until slightly wet.
Low pressure hand held equipment for indoor uses and hand pressurized or power operated sprayers for outdoor use sites	K-Othrine® SC Insecticide 4.75% ai (432-763) (contains 0.42 lbs ai/gal)	Indoor use – 0.005 lb ai/gal Outdoor perimeter - 0.214 lb ai/A or 0.005 lb ai/gal Turf – 0.13 lb ai/A Ornamentals- 0.00026 lb ai/gal	NA	NA	Indoor applications are to be made as spot or crack and crevice applications. Do not apply as a space spray and do not treat entire floor, carpet or coverings. Outdoor applications are to be made as building perimeter treatments or broadcast to lawns, recreational grounds and ornamentals.
	Delta Wettable Powder 5% ai	0.005 lb ai/gal	NA	NA	Indoor applications are to be made as spot or

[3] Available: http://www.epa.gov/pesticides/science/residential-exposure-sop.html

Table 4.1. Summary of Registered Residential Uses for Deltamethrin.					
Method of Application	**Product and Formulation (Reg. No.)**	**Application Rate**	**Maximum No. Applications per Season**	**Maximum Seasonal Application Rate (lb ai/A)**	**Use Directions, Application Timing, Type and Limitations**
	(432-832)				crack and crevice applications. Do not apply as a space spray and do not treat entire floor, carpet or coverings. Outdoor applications are to be made as broadcast to lawns, recreational grounds and ornamentals as a general surface spray.
Hose-end Sprayer or hand held pressurized sprayer	RUC-415 Insecticide 4.75% ai (432-805)	Lawn – 0.005 lb ai/gal Perimeter – 0.0023 lb ai/gal	Repeat as needed for lawns and every 7 to 10 days for ornamentals if needed.	NA	For use by homeowners for use on lawns, ornamentals, decks, foundations, patios and other outdoor areas.
Ready-to-Use Container, hand duster, or bulbous duster	Green Light Many Purpose Dust 0.05% ai (73327-14)	Crack and crevice- 0.00000025 lb ai/ft^2 Home vegetable garden – 0.00000066 lb ai/ft^2	Repeat at 7-day intervals as necessary.	NA	Apply indoors to crack and crevices. Do not apply as a broadcast application or to mattresses. For ornamental and home garden use apply thin layer of dust on upper and lower sides of leaves, stems and flowers
Granular Spreader	Delta Granules 0.1% ai (4-422)	0.000003 lb ai/ft^2 or 0.13 lb ai/A	Repeat as needed	NA	Apply to home lawns, under shrubbery and other ornamental recreational turf grass areas.
Ready-to-Use	Deltamethrin 4% Pet Collar for Dogs 4 % ai (68451-1)	0.0024 lb ai/pet	Reapply new collar every six months	NA	Use only on dogs to control fleas and ticks. Do not use on puppies under 12 weeks old.
Brush, roller or conventional airless equipment	Bug Juice Insecticide Additive 4.75% ai	0.005 lb ai/gal/can	NA	NA	Add 1 2/3 or 8 1/3 fluid ounces to either 1 or 5 gallons of latex coating, oil base coating, stains or sealers then mix well

Table 4.1. Summary of Registered Residential Uses for Deltamethrin.					
Method of Application	**Product and Formulation (Reg. No.)**	**Application Rate**	**Maximum No. Applications per Season**	**Maximum Seasonal Application Rate (lb ai/A)**	**Use Directions, Application Timing, Type and Limitations**
	(47332-11) 0.42 lb ai/gal				to proper dilution. Apply product in and on residential and non-residential buildings and structures including residential kitchens and all types of food handling establishments. Do not apply as a broadcast interior application.

5.0 Residential Exposure and Risk Estimates

This document provides a revised residential handler and post-application exposure assessment for existing residential indoor, outdoor, pet, and paint preservative uses that were evaluated in the 2004 ORE assessment (M. Collantes, D307927, Oct. 14, 2004). The revised assessments reflect updates to HED's 2012 Residential SOPs[4], along with policy changes for body weight assumptions, updated inhalation and incidental oral toxicological endpoints and doses, and reduced FQPA Safety Factors for adult and children's populations. The revised residential exposure estimates have been provided for the purpose of updating the aggregate human health risk assessment for deltamethrin.

5.1 Residential Handler Exposure/Risk Estimates for Registered Uses

A residential handler exposure assessment was previously performed for existing residential indoor, outdoor, turf, pet, and paint uses in the 2003 and 2004 occupational and residential exposure assessments (D287835, M. Collantes, 7/18/2003; and D307927, M. Collantes, 10/14/2004). Risk estimates for these registered residential scenarios have been revised to reflect updates to HED's 2012 Residential SOPs[5], along with policy changes for body weight assumptions and updated toxicological endpoints. In addition, HED has further revised the assessment to incorporate the general approach for pyrethroids in light of the cumulative risk assessment, i.e., the FQPA safety factor was reduced to 1X for adults and children >6 years old, and to 3X for children <6 years old.

Since the deltamethrin labels do not identify these residential use products as a restricted use, a revised residential handler exposure assessment was performed to be protective of potential homeowners who apply deltamethrin as indoor, outdoor, turf, paint, and pet treatments. The

[4] Available: http://www.epa.gov/pesticides/science/residential-exposure-sop.html
[5] Available: http://www.epa.gov/pesticides/science/residential-exposure-sop.html

quantitative exposure/risk assessment developed for the previously assessed residential handlers is based on the following (worse case) scenarios:

- Mix/Load/Apply liquid sprays using manually pressurized handwand for indoor spot and crack & crevice treatment,
- Mix/Load/Apply liquid (SC) sprays using hose-end sprayer for turf/lawn,
- Mix/Load/Apply liquid (SC) sprays using backpack sprayer for turf/lawn,
- Mix/Load/Apply wettable powder using manually pressurized handwand for turf/lawn,
- Mix/Load/Apply wettable powder using backpack sprayer for turf/lawn,
- Mix/Load/Apply paint additive using airless sprayer,
- Load/Apply granules using belly grinder to lawn/turf,
- Load/Apply granules using shaker can to outdoor sites,
- Apply aerosol spray to outdoor and indoor areas as a spot and crack & crevice treatment,
- Apply insecticidal dust to outdoor crack and crevice sites using shaker can, and
- Apply pet collar to dogs.

Summary of Residential Handler Exposure and Risk Estimates

Representative (worst case) registered residential uses were reassessed using the revised 2012 Residential SOPs and revised inhalation endpoints and doses. All residential handler scenarios resulted in inhalation risk estimates greater than the LOC (MOEs ≥ 100) and are not of concern. The exposure estimates are summarized for the worst-case residential handler exposure scenario for each registered product in **Table 5.1**.

Table 5.1. Residential Handler Exposure and Risk Estimates for Deltamethrin Registered Uses.

Exposure Scenario	Level of Concern	Inhalation Unit Exposure (mg/lb ai)	Maximum Application Rate[1]	Area Treated or Amount Handled Daily[2]	Inhalation	
					Dose (mg/kg/day)[3]	MOE[4]
Mix/Load/Apply						
Manually Pressurized Handwand for Indoor Crack & Crevice and Mattress Treatment K-Othrine SC Insecticide (4.75% ai) Reg. No.432-763	100	1.1	0.005 lb ai/gal	0.5 gals	0.000034	43,000
Hose-end Sprayer – Turf K-Othrine SC Insecticide (4.75% ai) Reg. No.432-763		0.022	0.13 lb ai /A	0.5 A	0.000018	83,000
Back Pack- Garden and Trees K-Othrine SC Insecticide (4.75% ai) Reg. No.432-763		0.14	0.005 lb ai/gal	5 gals	0.000044	34,000
Manually Pressurized Handwand and Backpack – Lawn/Turf and Gardens/Trees		1.1	0.005 lb ai/gal	5 gals	0.00034	4,300

Table 5.1. Residential Handler Exposure and Risk Estimates for Deltamethrin Registered Uses.						
Exposure Scenario	**Level of Concern**	**Inhalation Unit Exposure (mg/lb ai)**	**Maximum Application Rate[1]**	**Area Treated or Amount Handled Daily[2]**	**Inhalation**	
					Dose (mg/kg/day)[3]	**MOE[4]**
Delta Wettable Powder (5% ai) Reg. No. 432-832						
Airless Sprayer Bug Juice Insecticidal Additive (4.75% ai) Reg. No. 47332-11		0.56	0.005 lb ai/gal/can	5 one gal cans	0.00018	8,500
Load/Apply						
Belly Grinder Delta Granules (0.1% ai) Reg. No. 4-422	100	0.039	0.000003 lb ai/ft^2	1200 ft^2	0.0000018	850,000
Apply						
Shaker Can – Garden/Trees Many Purpose Dust RTU (0.05% ai) Reg. No. 73327-14	100	18	0.00000066 lb ai/ft^2	1200 ft^2	0.00018	8,400
Aerosol Spray – Garden/Trees D-Force Insecticide (0.06% ai) Reg. No. 279-9554		3	0.00075 lb ai/can	2 cans	0.000056	26,000
Aerosol Spray – Indoor Crack & Crevice and Mattress D-Force Insecticide (0.06% ai) Reg. No. 279-9554				0.5 can	0.000014	110,000
Ready-to-Use Pet Collar (4% ai) Reg. No. 4-422		negligible	0.0024 lb ai/pet	2 pet	NA	

1 Based on registered or proposed labels.
2 Based on HED's 2012 Residential SOPs (http://www.epa.gov/pesticides/science/residential-exposure-sop.html).
3 Inhalation Dose = Inhalation Unit Exposure (mg/lb ai) × Application Rate × Area Treated or Amount Handled ÷ Body Weight (80 kg).
4 Inhalation MOE = Inhalation NOAEL (1.49 mg/kg/day) ÷ Inhalation Dose (mg/kg/day).

5.2 Residential Post-application Exposure/Risk Estimates for Registered Uses

There is the potential for post-application exposure for individuals resulting from being in an environment that has been previously treated with deltamethrin. A residential post-application exposure assessment and amendment were previously performed for existing residential indoor, outdoor, lawn, pet and paint uses in 2003 and 2004 (D287835, M. Collantes, 7/18/2003; and D307927, M. Collantes, 10/14/2004). Risk estimates for these registered residential scenarios,

have been revised to reflect updates to HED's 2012 Residential SOPs[6], along with policy changes for body weight assumptions and updated toxicological endpoints. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios:

- Incidental oral (hand-to-mouth and object-to-mouth) contact with residues deposited on lawn/turf resulting from liquid and granular formulations;
- Incidental oral (soil ingestion) contact with residues deposited on lawn/turf resulting from liquid and granular formulations;
- Episodic Granular Ingestion resulting from granular formulations;
- Incidental oral (hand-to-mouth and object-to-mouth) contact with residues deposited on indoor surfaces from spot and crack & crevice treatments resulting from liquid formulations;
- Inhalation exposure of residues resulting from exposure to indoor pesticide vapors from liquid formulations; and
- Incidental oral (hand-to-mouth) contact with residues from treated dogs using pet collars.

The lifestages selected for each post-application scenario are based on an analysis provided as an Appendix in the 2012 Residential SOPs[7]. These lifestages are not the only lifestages that could be potentially exposed for these post-application scenarios; however, the assessment of these lifestages is health protective for the exposure and risk estimates for any other lifestages. HED further notes that there are chemical-specific and pyrethroid-specific studies available for assessing post-application exposure to deltamethrin on indoor surfaces (deltamethrin) and via inhalation (pyrethroid).

Residential Post-application Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the residential post-application risk assessment. Each assumption and factor is detailed in the 2012 Residential SOPs. The following two justifications explain why specific post-application scenarios were not conducted for indoor crack and crevice inhalation exposure, and exposure to treated paints and preservatives. A brief summary of a recently submitted chemical specific residue transfer petting study is also provided to support the registered pet collar use.

1. Post-application Inhalation Exposure from Indoor Crack and Crevice/Bed Bug Use:

Chemical-specific post-application inhalation exposure data are not available for the use of deltamethrin as a crack and crevice nor as a bed bug use; however, an Office of Research and Development (ORD) exposure study that was performed in the U.S. EPA's IAQ Research House provided surrogate data using two other chemicals. The study simulated crack and crevice applications of four pesticides; two emulsifiable concentrate products applied via a handheld sprayer (permethrin and cypermethrin), one aerosol can product (propoxur), and one gel bait product (fipronil). The application pattern used in the study is considered a reasonable representation of an indoor crack and crevice application and/or an indoor application for bed

[6] Available: http://www.epa.gov/pesticides/science/residential-exposure-sop.html
[7] Available: http://www.epa.gov/pesticides/science/residential-exposure-sop.html

bugs. Permethrin and cypermethrin air concentrations were not found in any measurable quantities in any room in the research house.

Although the data are not chemical specific, the Non-dietary Exposure Task Force (NDETF) performed an analysis of pyrethroid surface deposition and hand press exposure data, and concluded the exposure data for one pyrethroid can generally be used to represent the entire chemical class. Based on this NDETF analysis, HED considers it appropriate to use the air concentration data from the ORD study as a surrogate for deltamethrin when it is applied as described on the registered label. HED does not have concerns for deltamethrin for the post-application inhalation exposure scenario given that all air concentration values were below the limit of quantitation in the ORD study. Therefore, a quantitative inhalation post-application exposure assessment was not conducted.

2.) Post-application Non-Dietary Ingestion Exposure Assessment for Treated Paints and Preservatives:

The HED Residential SOPs are intended to assess post-application incidental oral exposure resulting from the application of pesticide treated paint to on indoor or outdoor surfaces, such as home walls, outdoor decks and play-sets. The registered paint product, Bug Juice Insecticidal Additive (Reg. No. 47332-11), is intended for indoor use as a spot or crack and crevice treatment only. It is not intended for use as a broadcast interior application such as entire walls, ceilings, and floors. The product labeling states that it can be applied" in and around cabinets, behind and beneath equipment and appliances, window and door frames, floor drains and sinks." These sites are not typically sites frequented by small children or adults on a routine bases. Furthermore post-application inhalation exposure is expected to be negligible due to low vapor pressure (1.5×10^{-8} mmHg at 25° C). Therefore, incidental oral and inhalation post-application exposures are expected to be minimal and quantitative assessments were not performed for deltamethrin. However, a residential handler assessment was performed for this use and is expected to be protective of any post-application exposure.

3.) Chemical Specific Residue Transfer Petting Study

<u>Deltamethrin: Two month dislodgeable residue study of deltamethrin in beagle dogs treated with Scalibor® Protector Band; MRID# 49350101; D420043; March 2014; A. Prohaczik, D.M.V. Ph.D.; MSD Animal Health Innovation SAS, Beaucouze France:</u>

The purpose of the study was to measure the amount of deltamethrin that may be available for transfer from a dog haircoat while the dog is wearing a deltamethrin impregnated collar (Scalibor® Protector Band for Dogs, containing 4% active ingredient).

The study was conducted with 10 medium size dogs (9.7-14.4 kg) that were treated with the test product by attaching a single deltamethrin impregnated collar around the neck of each animal and cutting off any excess length of collar. The actual application amount ranged from 592-748 mg ai. Transferable residue samples were collected on cotton glove and nitrile glove dosimeters using petting simulations. Specifically, two cotton gloves were placed over a nitrile glove and fitted onto a mannequin hand. Using the mannequin hand, a sampler conducted 20 petting simulations per dog per sampling interval. Each petting simulation consisted of three strokes in

specified areas intended to cover the whole body surface beginning from the head and ending at the tail base. Samples were collected from each dog at the following intervals: two days prior to treatment, 4 hours after treatment and at 1, 7, 14, 28, and 56 days after treatment.

Samples were analyzed for deltamethrin using a high performance liquid chromatography-tandem mass spectrometry (HPLC-MS/MS) analytical method with a validated level of quantification (LOQ) of 0.01 µg/glove. Concurrent recovery samples were prepared at four or five fortification levels and run with each analytical batch. The deltamethrin residues were corrected with the average concurrent recovery from the fortification level closest to the sample residue level. Residues reported as below the LOQ were assigned a value of ½ LOQ and were not corrected for concurrent fortification recovery. The Registrant did not correct for concurrent recovery, and set residue values below the LOQ to zero. The residues in µg/glove, µg/cm^2 of dog surface area, and percent of applied dose transferred were also calculated.

The average total transferable deltamethrin residues (based on sum of all 3 gloves) decreased from 20.1 µg/glove at Day 0 (4 hours after application of the collar) to 7.97 µg/gloves at Day 7. Average residues then gradually increased to a maximum of 25.7 µg/gloves at Day 56. Results calculated based on the surface area of the entire dog (and percent of applied collar application rate) followed the same pattern. The average percent of original dose of deltamethrin transferred to gloves decreased from 0.00352 µg/cm^2 (0.0032%) at 4 hours after application of the collar to 0.00139 µg/cm^2 (0.0012%) at Day 7. Average percent then increased to a maximum of 0.00441µg/cm^2 (0.0040%) at Day 56. Although an increase of residues was observed, the percent of the applied collar application rate that is transferable was similar between Day 0 (0.003%) and Day 56 (0.004%).

The deltamethrin concentration vs. time interval profile was similar for eight out of the ten dogs: an initial decrease in residues from Day 0 through Day 7 or Day 14, generally followed by a slight increase in residues through Day 56. The remaining two dogs had slightly different concentration-time profiles. In one dog (#7), total deltamethrin residues decreased initially between Day 0 and Day 1 (28.3 to 13.0 µg/gloves), then increased up to 103.3 µg/gloves on Day 56 (~4x the average Day 0 value). In another dog (#10), total deltamethrin residues decreased initially between Day 0 and Day 1 (29.0 to 13.9 µg/gloves), followed by an increase up to a maximum of 55.3 µg/gloves at Day 28 and stabilization by Day 56 (52.1 µg/gloves).

The residues of deltamethrin over time did not dissipate steadily, and in fact increased toward the end of the sampling period. Currently, the default fraction of available residues (FAR = 0.02) based on a data set of liquid formulated pet products is used to estimate exposure. The new submitted data provides a significantly lower FAR value of 0.0032% for use in this deltamethrin pet collar assessment. This FAR value was used in this assessment to support and conduct an updated human health risk assessment for deltamethrin.

Episodic Granular Ingestion

The product, Delta Granules (Reg. No. 4-422) may be applied by a spreader to home lawns, under shrubbery and other ornamental recreational turf grass areas. The Residential SOP for Turf and Lawns was used to estimate post-application doses from incidental ingestion of pesticide granules applied to lawns and gardens. Ingestion of granules is considered an episodic

(or acute) event and not a routine behavior for children. Since HED does not believe that this would occur on a regular basis, the scenario is considered to be an acute poisoning rather than a short-term exposure typically assessed in HED's human health risk assessments. Furthermore, the registered label instructs the user to thoroughly water treated areas after application so that both granules and lawns are moistened to ensure granules dissolve properly.

In an effort to refine the post-application dose and respective MOE for incidental ingestion of granules, the default granular ingestion rate of 0.3 g/day was adjusted to 0.14 g/day to reflect the amount of product applied on a per area basis (3 lb/1000 ft^2). This adjustment resulted in a dose of 0.14 mg/kg/day and a MOE of 120. In order to achieve an MOE greater than the LOC (MOE $\geq$ 300), the application rate would need to be reduced from 0.000003 lb ai/ft^2 to 0.000001 lb ai/ft^2, which would result in a post-application dose of 0.005 and a MOE of 300.

Summary of Residential Post-application Non-Cancer Exposure and Risk Estimates

All the representative indoor/outdoor and pet incidental oral (hand-to-mouth) post-application scenarios resulted in risk estimates ranging from an MOE of 630 to 24,000 and are not of concern. A summary of the registered residential post-application exposure and risk estimates for deltamethrin is provided in **Table 5.2**

Table 5.2. Registered Residential Post-application Non-cancer Exposure and Risk Estimates for Deltamethrin.

Lifestage	Post-application Exposure Scenario		Application Rate[1]	Dose (mg/kg/day)[2]	MOEs[3]	Combined MOEs
	Use Site	Route of Exposure				
Adult	Indoor C&C K-Othrine SC Insecticide Reg. No.432-763 (0.06% ai)	Dermal	0.005 lb ai/ gal	NA	NA	NA
		Inhalation				
Child		Dermal		NA	NA	
		Inhalation				
		HTM		0.0000614	24,000	
		OTM		0.000039	38,000	
Adult	Indoor C&C and Mattress D-Force Ready-to-Use Aerosol Spray Reg. No. 279-9554	Dermal	0.00075 lb ai/can	NA	NA	
		Dermal Mattress				
		Inhalation				
Child		Dermal		NA	NA	
		Dermal Mattress				
		Inhalation				
		HTM		0.0023	630	
		OTM		0.00031	4700	
Adult	Lawn/Turf Delta Granules Reg. No. 4-422	Dermal	0.13 lb ai/A or 0.000003 lb ai/ft^2	NA	NA	NA
		Inhalation				
Child		Dermal		NA	NA	
		Inhalation				
		HTM		0.0002	7,600	
		OTM		0.00001	120,000	
		Soil Ingestion		0.000044	340,000	
		Episodic Ingestion		0.0127	120	
Adult	Lawn/Turf	Dermal	0.13 lb ai/A	NA	NA	
		Inhalation				

Table 5.2. Registered Residential Post-application Non-cancer Exposure and Risk Estimates for Deltamethrin.						
Lifestage	**Post-application Exposure Scenario**		**Application Rate[1]**	**Dose (mg/kg/day)[2]**	**MOEs[3]**	**Combined MOEs**
	Use Site	**Route of Exposure**				
Child	K-Othrine SC Insecticide Reg. No.432-763 (0.06% ai)	Dermal		NA	NA	
		Inhalation				
		HTM		0.002	750	
		OTM		0.00006	25,000	
		Soil Ingestion		0.000034	340,000	
Adult	4% Deltamethrin Pet Collar (Reg. No. 68451-1)	Dermal	0.0024 lb ai/pet	NA	NA	
		Inhalation				
Child		Dermal		NA	NA	
		Inhalation				
		HTM (small dog)		0.000014	11,000	
		HTM (medium size dog)		0.0000058	26,000	
		HTM (large dog)		0.0000037	400,000	

1 Based on registered or proposed label.
2 Dose (mg/kg/day) equations: see Appendixes B-D for specific equations used by exposure scenario.
3 MOE = POD (mg/kg/day) ÷ Dose (mg/kg/day).

Turf Transferable Residue (TTR) Data

In accordance with 40CFR158, TTR data are required for all occupational (e.g., sod farms, golf courses, parks, and recreational areas) or residential turf uses that could result in post-application exposure to turf. In the absence of chemical-specific TTR data, EPA uses default values. The 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment includes an analysis of all TTR data, available at the time, which resulted in the selection of revised liquid and granular default values for the fraction of the application rate available for transfer after a turf application (FAR). These values are based on an analysis of 59 TTR studies performed with the Modified California Roller Method (36 studies using liquids, 11 studies using wettable powders/water dispersible granules, and 12 studies using granules). The liquid results (N=131) indicate a range of FAR values from 0.0005% to 6.1% and the granular results (N=37) indicate a range of 0.00064% to 0.69%. In both the liquid and granular data, a large range of transferability is observed and this variability can potentially be attributable to many factors such as active ingredient; formulation; field conditions in the studies; weather conditions (e.g., humidity); or many other difficult to quantify factors. Although witnessed across multiple chemicals, this range in FAR values is not expected when considering TTR data for a single chemical. HED selected 1% and 0.2% as high-end default values for liquid and granular products, respectively. Because TTR data are not available for deltamethrin, EPA is using the default value of 1%. Although there may be a small degree of uncertainty in the use of the default TTR value for deltamethrin (i.e., there is a small chance that the FAR value may exceed the applicable default value), it is likely that the health-protective aspects of EPA's residential post-application turf assessment methodology will more than compensate for this potential uncertainty (i.e., the

methodology is likely to overestimate exposure by a factor greater than the factor than the highest measured FAR values exceed the defaults). For example, when assessing residential post-application turf exposure, EPA assumes the following: exposures occur to zero-day (i.e., day of application) residues every day of the assessed exposure duration (i.e., EPA assumes that no dissipation or degradation occurs, it doesn't rain, the grass is not mowed, etc); individuals perform the same post-application activities performed in the turf transfer coefficient study day after day (e.g., tumbling, playing on turf with toys, etc.); and individuals engage in these post application activities for a high-end amount of time every day that is represented by data reflecting time children spend outdoors and not specifically engaged in activities on turf, when in actuality children do not spend all of their outdoor time on turf and high-end levels of activity will not occur every day.

Given the conservatisms discussed above and the potential compounding nature of these conservatisms, EPA is able to rely upon the calculated exposure estimates with confidence that exposure is not being underestimated.

Since the estimated residential turf post-application exposure for [residential turf/mower/golf course] using default TTR values for deltamethrin is not minimal in comparison to the level of concern (i.e., the calculated MOE is not greater than 10 times higher than the level of concern, MOE = 750 compared to the LOC of 3000), future refinements of this post-application exposure for deltamethrin may be necessary due to increased use of deltamethrin or advances in EPA risk assessments. Therefore, EPA is requiring the 40 CFR TTR data requirement to facilitate any necessary exposure assessment refinements and to further EPA's general understanding of the availability of turf transferable pesticide residues.

5.4 Residential Risk Estimates for Use in Aggregate Assessment

The recommended residential exposure for the use in the adult aggregate assessment reflects the inhalation handler exposure resulting from the flea control scenario (i.e., treatment of lawns/turf and gardens/trees by manually pressurized handgun and backpack). This scenario resulted in a MOE of 4,300 and is not of concern.

The incidental oral (hand-to-mouth) post-application exposure resulting from control of bed bugs scenario was selected to estimate the child aggregate assessment. This scenario resulted in a MOE of 630 is not a risk of concern. A summary of the residential risk estimates for use in the aggregate assessment are provided in Table 5.4.

6.0 Occupational Exposure and Risk Estimates

There is no occupational exposure associated with this action to establish an import tolerance. Therefore, an occupational exposure assessment was not completed.

Table 5.4 Recommendation for Residential Exposures to be Included in the Deltamethrin Aggregate Assessment .[1]															
Lifestage	**Residential Handler**						**Residential Post-application**								
	Dose (mg/kg/day)[2]			**MOE[3]**			**Dose (mg/kg/day)**				**MOE**				
	Dermal	**Inhalation**	**Total**	**Dermal**	**Inhalation**	**Total**	**Dermal**	**Inhalation**	**Oral**	**Total**	**Dermal**	**Inhalation**	**Oral**	**Total**
Back Pack – Garden and Trees							**Bed Bug Scenario (Indoor)**							
Adult Male	NA	0.00034	NA	NA	**4,300**	NA	NA	N/A	N/A	NA	NA	N/A	N/A	NA
Adult Female														
Child	N/A								0.002				**630**	

1 Bolded risk estimates should contribute to the residential exposure portion of the aggregate assessment.
2 Combined Residential Handler Dose = the highest handler dose for each applicable lifestage of all scenarios assessed from Table 5.3.
3 Combined Residential Post-application MOE = the MOEs associated with the highest doses identified in Table 5.3.

APPENDIX A: Residential Handler Algorithms

1.0 Residential Handler Exposure Calculations

1.1 Turf, Gardens and Trees, Indoor Environments and Treated Pets

Dermal and Inhalation Handler Exposure Algorithm
Daily dermal and inhalation exposure (mg/day) for residential pesticide handlers, for a given formulation-application method combination, is estimated by multiplying the formulation-application method-specific unit exposure by an estimate of the amount of active ingredient handled in a day, using the equation below:

$$E = UE * AR * A$$

where:

E = exposure (mg/day);
UE = unit exposure (mg/lb ai);
AR = application rate (e.g., lb ai/ft^2, lb ai/gal); and
A = area treated or amount handled (e.g., ft^2/day, gal/day).

1.2 Treated Paints and Preservatives

Dermal and Inhalation Handler Exposure Algorithm
Daily dermal and inhalation exposure (mg/day) for residential pesticide handlers, for a given formulation-application method combination, is estimated by multiplying the formulation-application method-specific unit exposure by an estimate of the amount of active ingredient handled in a day, using the equation below:

$$E = UE * AR * N$$

where:

E = exposure (mg/day);
UE = unit exposure (mg/lb ai);
AR = application rate (e.g., lbs a.i./can); and
A = number of cans paint used per exposure day (cans/day).

The application rate can be calculated as follows:

$$AR = V * \rho * WF * CF1$$

where:

AR = Mass of active ingredient applied per paint can (lbs ai/can);
V = Volume of paint contained in each can (mL/can);
ρ = Paint density (g/mL);
WF = Weight fraction of a.i. in treated paint/preservative (% ai w/w); and

CF1 = Gram-to-pound conversion factor (2.2×10^{-3} lbs/g).

1.3 Residential Handler Dose Calculations

Dermal and/or inhalation absorbed doses normalized to body weight are calculated as:

$$D = E * AF / BW$$

where:

D = dose (mg/kg-day);
E = exposure (mg/day);
AF = absorption factor (dermal and/or inhalation); and
BW = body weight (kg).

APPENDIX B: Residential Turf Post-application Algorithm

B.1 Post-application Hand-to-Mouth Exposure Algorithm– Physical Activities on Turf

Exposure from hand-to-mouth activity is calculated as follows (based on the algorithm utilized in the SHEDS-Multimedia model):

$$E = [HR * (F_M * SA_H) * (ET * N\_Replen) * (1- (1- SE)^{(Freq\_HtM/N\text{-}Replen)})]$$

where:

E = exposure (mg/day);
HR = hand residue loading (mg/cm^2);
FM = fraction hand surface area mouthed / event (fraction/event);
SAH = typical surface area of one hand (cm^2);
ET = exposure time (hr/day);
N_Replen = number of replenishment intervals per hour (intervals/hour);
SE = saliva extraction factor (i.e., mouthing removal efficiency); and
Freq_HtM = number of hand-to-mouth contacts events per hour (events/hour).

and

$$HR = \frac{Fai_{hands} * DE}{SA_H * 2}$$

where:

HR = hand residue loading (mg/cm^2);
Fai_{hands} = fraction ai on hands compared to total surface residue from dermal transfer coefficient study (unitless);
DE = dermal exposure (mg); and
SA_H = typical surface area of one hand (cm^2).

Dose, normalized to body weight, is calculated as:

$$D = \frac{E}{BW}$$

where:

D	= dose (mg/kg-day);
E	= exposure (mg/day); and
BW	= body weight (kg).

Table B.1: Turf (Physical Activities) – Inputs for Residential Post-application Hand-to-Mouth Exposure.			
Algorithm Notation	**Exposure Factor (units)**		**Point Estimate(s)**
Fai_{hands}	Fraction of ai on hands from dermal transfer coefficient study (unitless)	Liquid formulations	0.06
		Granular formulations	0.027.
DE	Dermal exposure (mg)		Calculated
SA_H	Typical surface area of one hand (cm^2), children 1 < 2 years old		150
AR	Application rate (mass active ingredient per unit area)		**0.13 lb ai/A or 0.000003 lb ai/ft2**
HR	Residue available on the hands (mg/cm^2)		Calculated via (DE * Fai_{hands})/SA_H
F_M	Fraction hand surface area mouthed (fraction/event)		0.127
N_Replen	Replenishment intervals per hour (intervals/hr)		4
ET	Exposure time (hrs/day)		1.5
SE	Saliva extraction factor (unitless)		0.48
Freq_HtM	Hand-to-mouth events per hour (events/hr)		13.9
BW	Body Weight (kg)	Children 1 < 2 years old	11

B.2 Post-application Episodic Granular Ingestion Exposure Algorithm– Physical Activities on Turf

Exposure from incidental ingestion of pesticide pellets or granules is calculated as follows:

$$E = GIgR^* FD * CF1$$

where:
E = exposure (mg/day);
GIgR = ingestion rate of dry pesticide formulation (g/day);
FD = fraction of ai in dry formulation (unitless); and
CF1 = weight unit conversion factor (1,000 mg/g).

Dose, normalized to body weight, are calculated as:

$$D = \frac{E}{BW}$$

where:

D	=	dose (mg/kg-day);
E	=	exposure (mg/day); and
BW	=	body weight (kg).

TableB.3: Turf (Physical Activities) – Inputs for Residential Post-application Episodic Granular Ingestion Exposure

Algorithm Notation	Exposure Factor (units)		Point Estimate(s)
F_D	Fraction of active ingredient in dry formulation		**0.1%**
AR	Application rate (lbs/A or lbs/1,000 ft^2)		**3 lbs./1000ft^2**
GIgR	Granule ingestion rate per day (g/day) [1]		0.3
BW	Body Weight (kg)	Children 1 < 2 years old	11

[1] See discussion below on how this value may be adjusted if product specific information is available.

The assumed ingestion rate for dry pesticide formulation (e.g. granules) is 0.3 gram/day for children 1 < 2 years old. For purposes of refining the estimated ingested dose, the granular ingestion rate may be adjusted to reflect the amount of product applied on a per area basis.

APPENDIX C: Indoor Environment Post-Application Algorithms

Post-application Hand-to-Mouth Exposure Algorithm

Exposure from hand-to-mouth activity is calculated as follows (based on algorithm utilized in SHEDS-Multimedia):

$$E = \left[HR * \ (F_M * \ SA_H) * \ (ET * N\_Replen) * \left(1 - (1 - SE)^{\frac{Freq\_HtM}{N\_Replen}}\right)\right]$$

where:

E	= exposure (mg/day);
HR	= hand residue loading (mg/cm^2);
F_M	= fraction hand surface area mouthed / event (fraction/event);
ET	= exposure time (hr/day);
SA_H	= surface area of one hand (cm^2);
N_Replen	= number of replenishment intervals per hour (intervals/hour);
SE	= saliva extraction factor (i.e., mouthing removal efficiency); and
Freq_HtM	= number of hand-to-mouth contacts events per hour (events/hour).

and

$$HR = \frac{Fai_{hands} * DE}{SA_H * 2}$$

where:

HR	= hand residue loading (mg/cm^2);
Fai_{hands}	= fraction ai on hands compared to total surface residue from jazzercise study (unitless);
DE	= dermal exposure (mg); and
SA_H	= typical surface area of one hand (cm^2).

and

Dose, normalized to body weight, is calculated as:

$$D = \frac{E}{BW}$$

where:

D	= dose (mg/kg-day);
E	= exposure (mg/day); and
BW	= body weight (kg).

Table C: Indoor Environments – Inputs for Residential Post-application Hand-to-Mouth Exposure.				
Algorithm Notation	**Exposure Factor (units)**			**Point Estimate(s)**
Fai_{hands}	Fraction of ai on hands from jazzercise study (unitless)			0.15
DE	Dermal exposure calculated (mg)			0.2
HR	Residue available on the hands (mg/cm^2)			0.0001
SA_H	Surface area of one hand (cm^2)	Children 1 < 2 years old		150
AR	Application rate (mass active ingredient per unit area)			0.000005 lb ai/ft^2
F_M	Fraction of hand mouthed per event (fraction/event)			0.13
N_Replen	Replenishment intervals per hour (intervals/hr)			4
ET	Exposure time (hours per day)	Children 1 < 2 years old	Carpets	4
			Hard Surfaces	2
SE	Saliva extraction factor (fraction)			0.48
Freq_HtM	Hand-to-mouth events per hour (events/hr)	Children 1 < 2 years old		20
BW	Body Weight (kg)	Children 1 < 2 years old		11

APPENDIX D: Treated Pets Post-application Algorithm

D.1 Post-application Dermal Exposure Algorithm

The following method is used to calculate dermal exposures that are attributable to an adult or child contacting a treated companion pet:

$$E = TC * TR * ET$$

where:

E = exposure (mg/day);
TC = transfer coefficient (cm^2/hr);
TR = transferable residue (mg/cm^2); and
ET = exposure time (hours/day).

$$TR = \frac{AR * F_{AR}}{SA}$$

where:

TR = transferable residue (mg/cm^2);
AR = application rate or amount applied to animal (mg);
F_{AR} = fraction of the application rate available as transferable residue; and
SA = surface area of the pet (cm^2).

Absorbed dermal dose, normalized to body weight, is calculated as:

$$D = \frac{E * AF}{BW}$$

where:

D = dose (mg/kg-day);
E = exposure (mg/day);
AF = absorption factor (dermal); and
BW = body weight (kg).

Table D.1: Treated Pets – Inputs for Residential Post-application Dermal Exposure			
Algorithm Notation	**Exposure Factor Units**		**Point Estimates**
AR	Application rate (mg)		**1000 mg**
SA	Surface Area of Animal (cm^2)	Small Cat, Dog	Cat – 1,500 Dog – 3,000
		Medium Cat, Dog	Cat – 2,500 Dog – 7,000
		Large Cat, Dog	Cat – 4,000 Dog – 11,000
F_{AR}	Fraction of AR Available for Transfer		**0.000032**
TC	Transfer Coefficient – Liquids (cm^2/hr)	Adult	5,200
		Children 1 < 2 years old	1,400
	Transfer Coefficient – Solids (cm^2/hr)	Adult	140,000
		Children 1 < 2 years old	38,000
ET	Exposure Time (hours per day)	Adult	0.77
		Children 1 < 2 years old	1.0
BW	Body weight (kg)	Adult	80
		Children 1 < 2 years old	11

D.2 Post-application Hand-to-Mouth Exposure Algorithm

Exposure from hand-to-mouth activity is calculated as follows (based on algorithm utilized in SHEDS-Multimedia):

$$E = [HR * (F_M * SA_H) * (ET * N\_Replen) * (1- (1- SE)^{(Freq\_HtM/N-Replen)})]$$

where:

E = exposure (mg/day);
HR = hand residue loading (mg/cm^2);
SA_H = surface area of one child hand (cm^2);
F_M = fraction hand surface area mouthed /event (fraction/event);
ET = exposure time (hr/day);
N_Replen = number of replenishment intervals per hour (intervals/hour);
SE = saliva extraction factor (i.e., mouthing removal efficiency); and
Freq_HtM = number of hand-to-mouth contacts events per hour (events/hour).

and

$$HR = \frac{E * Fai_{hands}}{2 * SA_H}$$

where:

HR = hand residue loading (mg/cm^2);
E = dermal exposure (mg);
Fai_{hands} = fraction of ai on hands compared to total residue from dermal transfer coefficient study (unitless); and
SA_H = surface area of one child hand (cm^2).

Oral dose, normalized to body weight, is calculated as:

$$D = \frac{E}{BW}$$

where:

D = dose (mg/kg-day);
E = exposure (mg/day); and
BW = body weight (kg).

Table D.2: Treated Pets – Inputs for Residential Post-application Hand-to-Mouth Exposure.

Algorithm Notation	Exposure Factor (units)		Point Estimate(s)
Fai_{hands}	Fraction of ai on hands from transfer coefficient studies (unitless)		Liquid = 0.040
F_M	Fraction hand surface area mouthed /event (fraction/event)		0.13
N_Replen	Replenishment intervals per hour (intervals/hr)		4
ET	Exposure time (hours/day)	Children 1 < 2 years old	1.0
SE	Saliva extraction factor		0.48
Freq_HtM	Hand-to-mouth events per hour (events/hr)	Children 1 < 2 years old	20
SA_H	Typical surface area of one child hand (cm^2)	Children 1 < 2 years old	150
BW	Body Weight (kg)	Children 1 < 2 years old	11